

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE: Application of Michelle L. DAWSON et al.

Serial No.: 10/595,449

Art Unit: 1626

Filing Date: April 20, 2006

Examiner: To be assigned

For: *Inhalable Pharmaceutical Formulations
Employing Lactose Anhydrate and
Methods of Administering the Same*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicants request that the references identified on Form PTO-1449 appended hereto be considered by the Examiner and officially made of record in accordance with the provisions of 37 CFR 1.97

- ☒ Copies of the references are enclosed
- ☐ Copies of the references were submitted in parent application Serial No. _____. (37 CFR 1.98(d))
- ☐ A copy of the International Search Report which issued on International Application No. _____ is submitted herewith. All of the publications cited in the International Search Report are listed on the attached form PTO-1449 and Applicants understand that copies have been supplied to the U.S. Patent Office by the International Bureau.
- A. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing date of the above application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 CFR 1.97(b).
- OR
- ☐ **The Information Disclosure Statement submitted herewith is being filed before the mailing of a first office action after the filing of a Request For Continued Examination under 37 C.F.R. 1.114 (37 C.F.R. 1.97(b)(4)).**
- B. ☐ The Information Disclosure Statement transmitted herewith is being filed **after** three months of the filing date of the above application or the date of entry into the national stage as set forth in § 1.491 of an international application or after the mailing date of the first Office Action on the merits, whichever event occurred last, but **before** the mailing date of either:
- (1) a final action under § 1.113 or
- (2) a notice of allowance under § 1.311,
- whichever occurs first.
- ☐ Applicant hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ Applicant elects the option to pay the fee set forth in 37 CFR 1.17(p) for submission of an Information Disclosure Statement under § 1.97(c) (\$180.00).

- C. ☐ The Information Disclosure Statement transmitted herewith is being filed **after** a final action under § 1.113, or a notice of allowance under § 1.311, whichever occurs first, but before the payment of the issue fee. Also enclosed is a copy of the International Search Report which Issued on International Publication No.

In accordance with the requirements of 37 CFR 1.97(d):

- ☐ Applicant hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement. **[or]**
- ☐ Applicant hereby certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this statement; and
- ☐ The petition fee set forth in § 1.17(i)(1) (\$180.00) is submitted herewith.

☒ Please charge any required fees to Deposit Account No.07-1392.

☐ A duplicate copy of this paper is attached.

Respectfully Submitted,

/Robert J. Smith/
Robert J. Smith
Attorney of Record
Registration No. 40,820

Date: June 8, 2007
GlaxoSmithKline
Corporate Intellectual Property
5 Moore Drive, P.O. Box 13398
Research Triangle Park, NC 27709-3398
Telephone: (919) 483- 9616
Facsimile: (919) 483-7988

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT				SERIAL NO.		10/595,449	
				FILING DATE		April 20, 2006	
				APPLICANT		Michelle L. DAWSON	
				GROUP		To be assigned	
				EXAMINER		To be assigned	
				ATTORNEY DOCKET NO.		PR60375USw	
U.S. PATENT DOCUMENTS							
Examiner Initials		Patent Number	Issue Date	Name	Class	Subclass	Filing Date If Appropriate
	1.	4,778,054	10/18/1988	Newell et al.			
	2.	4,811,731	03/14/1989	Newell et al.			
	3.	5,035,237	07/30/1991	Newell et al.			
	4.	5,590,645	01/07/1997	Davies et al.			
	5.	5,860,419	01/19/1999	Davies et al.			
	6.	5,873,360	02/23/1999	Davies et al.			
	7.	6,032,666	03/07/2000	Davies et al.			
	8.	6,143,277	11/07/2000	Ashurst et al.			
	9.	6,170,717	01/09/2001	DiGiovanni et al.			
	10.	6,253,762	07/03/2001	Britto			
	11.	6,315,173	11/13/2001	DiGiovanni et al.			
Continue on page <u>2</u>							
FOREIGN PATENT DOCUMENTS							
		Document Number	Publication Date	Country	Class	Subclass	Translation Yes No
	12.	GB2064336	06/17/1981	GB			
	13.	GB2129691	05/23/1984	GB			
	14.	GB2169265	07/09/1986	GB			
	15.	GB2178965	02/25/1987	GB			
	16.	GB2242134	09/25/1991	GB			
	17.	WO 95/24889	09/21/1995	PCT			
	18.	WO 98/16205	04/23/1998	PCT			
Continue on page <u>2</u>							
OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)							
	19.	Figura et al., "Anhydrous α -Lactose A study with DSC and TXRD," <i>Journal of Thermal Analysis</i> 44 :45-53 (1995).					
	20.	Ganderton et al., "Dry Powder Inhalers," <i>Advances in Pharm Sci.</i> 165-191 (1992).					
	21.	Hickey et al., "Factors influencing the dispersion of dry powders as aerosols," <i>Pharm. Tech.</i> 58-82 (Aug. 1994).					
	22.	Jashnani et al., "Testing of dry powder aerosol formulations in different environmental conditions" <i>Int. J. Pharm.</i> 113 :123-130 (1995).					
	23.	Jashnani et al., "Dry powder aerosol generation in different environments: performance comparisons of albuterol sulfate, albuterol adipate and albuterol stearate," <i>Int. J. Pharm.</i> 130 :13-24 (1996).					
Continue on page <u>2</u>							
EXAMINER					DATE CONSIDERED		
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.							

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT				SERIAL NO.		10/595,449	
				FILING DATE		April 20, 2006	
				APPLICANT		Michelle L. DAWSON	
				GROUP		To be assigned	
				EXAMINER		To be assigned	
				ATTORNEY DOCKET NO.		PR60375USw	
U.S. PATENT DOCUMENTS							
Examiner Initials		Patent Number	Issue Date	Name	Class	Subclass	Filing Date If Appropriate
	24.	6,318,603	11/20/2001	Burt			
	25.	6,321,747	11/27/2001	Dmitrovic et al.			
	26.	6,360,739	03/26/2002	Rand et al.			
	27.	6,378,519	04/30/2002	Davies et al.			
	28.	6,390,291	05/21/2002	Garrill et al.			
	29.	6,431,168	08/13/2002	Rand et al.			
	30.	6,511,653	01/28/2003	Britto et al.			
	31.	6,532,955	03/18/2003	Ashurst et al.			
	32.	6,536,427	03/25/2003	Davies et al.			
	33.	6,546,928	04/15/2003	Ashurst et al.			
	34.	6,645,466	11/11/2003	Keller et al.			
Continue on page _____							
FOREIGN PATENT DOCUMENTS							
		Document Number	Publication Date	Country	Class	Subclass	Translation Yes No
	35.	WO 98/41193	09/24/1998	PCT			
	36.	EP 0876814	11/11/1998	EPO			
	37.	WO 00/28979	05/25/2000	PCT			X(Abstract)
	38.	WO 00/71419	11/30/2000	PCT			
	39.	WO 00/78386	12/28/2000	PCT			
	40.	EP 1192946	04/03/2002	EPO			
Continue on page _____							
OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)							
	41.	Maggi et al., "Influence of the moisture on the performance of a new dry powder inhaler," <i>Int. J. Pharm.</i> 177(1) :83-91 (1999).					
	42.	Mueller-Waltz et al., "Skye Protect™ - A novel approach to improved stability of dry powders for inhalation," Drug Delivery To The Lungs XI, The Aerosol Society, London 26-29 (2000).					
	43.	Wetterlim, "Turbuhaler: a new powder inhaler for administration of drugs to the airways," <i>Pharm. Res.</i> 5(8) :506-508 (1988).					
	44.	Williams et al., "Investigation of moisture scavengers in pressurized metered-dose inhalers," <i>STP Pharma Sci</i> 10(3) :243-250 (2000).					
Continue on page _____							
EXAMINER					DATE CONSIDERED		
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.							